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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,968	07/13/2001	Gregory G. Germino	JHU1680-2	3795

7590 05/23/2002

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EXAMINER

SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/904,968	GERMINO ET AL.	
	Examiner	Art Unit	
	Sally A Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-67 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                            | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____                                    |

***RESTRICTION***

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Groups 1-43, Claims 1-66, drawn to primers consisting of SEQ ID NOS: 3-18, nested primer pairs consisting of SEQ ID NOS: 19-50, 51 and 61 and SEQ ID NOS: 62 to 96, 113, and 97 to 112, polynucleotides containing PDK1 mutations located in regions amplified by said primer pairs, methods of detecting a mutation in a polynucleotide region, a kit containing primers to amplify a polynucleotide region, a kit containing a probe that hybridizes to the polynucleotide region as classified in Class 435 subclass 6.

II. Group 44, Claim 67 drawn to a kit comprising detecting a mutation in the PKD1 gene by the binding of an antibody as classified in Class 435 subclass 7.1.

a. Groups 1-44 include inventions that are patentably distinct in structure and physiochemical properties. Inventions in Groups 1-44 are each drawn to different nucleic acid sequences. Because nucleic acids are composed of nucleotides in a myriad arrangement of base pairs wherein this arrangement can dictate various secondary structures and innumerable different resulting properties characteristic to each individual nucleotide molecule, the inventions have different structural and functional properties. Furthermore, the compositions are utilized in different methodologies, such that each claimed nucleic acids may be utilized in hybridization assays to only a specific polynucleotide region. No Group requires the invention of another since the nucleic acids of each invention can be used in many different ways and have many different characteristics including their primary and secondary sequences and resulting properties.

b. Group 45 and each of Groups 1-44 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the nucleic acids of inventions 1-44 are not required to practice the methods of invention 45 involving antibodies.

**Sequence Election Requirement Applicable to All Groups:**

3. Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differs in structure and in function and in biological activity. A restriction is applied to each Group. For an elected Group drawn to a nucleotide sequence, the Applicants must elect a single primer pair from nucleic acid sequences SEQ ID NOS: 3-18, a single nested primer pair that corresponds to the elected primer pair consisting of SEQ ID NOS: 19-50, 51 and 61 and SEQ ID NOS: 62 to 96, 113, and 97 to 112, and a single polynucleotide region containing a mutation as specified in Claim 20 that is detected specifically by the elected primer pair and nested primer pair. (See MPEP 803.04). In addition the restriction will also apply to the method and kit claims wherein only the single, elected primer pair, nested primer pair, and polynucleotide region containing a mutation will be included in the elected method and kit. For example, if Applicant elects Group I, SEQ ID NOS: 3 and 4, nested primer pair SEQ ID NOS: 19 and 20, polynucleotides containing PDK1 mutations located in regions amplified by said nested primer pairs, the method of

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detecting this specific region with these specific nested primer pairs, and the kit containing these same primer pairs to amplify the specific region will be examined.

**Applicant is advised that examination will be restricted to only the elected SEQ ID NO. and should not to be construed as a species election.**

The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. Similarly, proteins comprising unique amino acid sequences are structurally and functionally distinct. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter and because these inventions require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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6. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Friday from 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703)308-1152. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantai Dessau whose telephone number is (703)605-1237.

Sally Sakelaris

*Sally Sakelaris*  
5/22/02

*Lisa B. Arthur*

LISA B. ARTHUR  
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